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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,558	07/13/2001	Carl W. Garnaat	1016	2761

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PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 08/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/905,558

Applicant(s)

GARNAAT ET AL.

Examiner

Medina A Ibrahim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-32 and 41-52 is/are rejected.
- 7) ☒ Claim(s) 37-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed on 06/12/03 in reply to the Office action mailed 03/12/03 has been entered. New claims 37-52 are added. Therefore, claims 1-52 are pending in this application.

Claims 15-32 and 37-52 are under examination.

Claims 1-14 and 33-36 are withdrawn from consideration as being directed to the non-elected invention.

All previous rejections and objections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 15-32 and 37-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reasons of record as set forth in the Office action of 03/12/03. Applicant's arguments filed on 06/12/03 have been considered but are not deemed persuasive.

Claim 15 is indefinite because the metes and bounds of "operable fragments" in claim 15 (b) are unclear, as stated in the last Office action. Applicant argues that "operable fragments" as defined in the specification is clear to one skilled in the art. Therefore, the rejection should be withdrawn (response, paragraph bridging pages 10-11). Examiner responds that while "operable fragments" is not hard to understand, the definition provided on pages 21 and 22 of the specification does not clearly set forth the

boundaries of the claimed invention, and hence the phrase is open to individual interpretations, such as a "fragment of 2 base pairs from any male-tissue specific gene promoter" and a "fragment of 2 base pairs from any promoter". Therefore, the rejection is maintained for claims 15-32.

Claims 37-40 are indefinite in the recitation of " selected from the group consisting of: nucleic acids" because only one ATCC deposit accession number for one nucleic acid is recited.

Claim Rejections - 35 USC § 112

1. Claims 15-32 and 41-52 are rejected under 35 U.S.C. 112, **first paragraph**, because the specification is only enabling for claims limited the isolated polynucleotides SEQ ID NO: 16, a recombinant expression cassette comprising said polynucleotide operably linked to an encoding polynucleotide of interest, transgenic plants and seed comprising said recombinant expression cassette, and a method of altering expression of a gene of interest in a transgenic plant . The rejection is repeated for the reasons of record as set forth in the Office action of 03/12/03. Applicant's arguments filed on 6/12/03 have been fully considered but are not deemed persuasive.
2. Applicant argues that the instant specification provides guidance with respect to modification of the disclosed sequences because two ZmAxig1 promoter sequences (in V1 and V2) of different length having the desired promoter function have been disclosed. Applicant asserts that further promoter sequences can be logically inferred from the structure and corresponding 4 and 5 adenine residues of the V1 and V2 promoters, respectively (response, paragraph bridging pages 13 and 14). Applicant

further argues that the reference by Kim et al and Benfey et al cited by the Examiner in support of the rejection do not adequately reflect the state of the art. Applicant asserts that the techniques for analysis of promoter fragments and deletion or systematic substitution followed by appropriate expression assays are routine in the art, and do not constitute undue experimentation. Applicant concludes that given the disclosed full length and partial ZmA_{xg1} promoter sequence as the starting point and the sufficient support for deletion analysis and site directed mutagenesis known in the art, one skilled in the art would be able to determine functional fragments of the disclosed sequences routinely. Applicant requests that the rejection be withdrawn (response, pages 15-16).

3. These arguments are not persuasive. The claimed invention encompasses functional fragments of varying lengths of SEQ ID NO: 16 as well as sequences having at least 75% sequence identity to SEQ ID NO: 16 and hybridizing sequences that retains the promoter activity of SEQ ID NO: 16. While deletion analysis and site directed mutagenesis are known, it is not routine in the art to screen for multiple deletions or multiple modifications in a tissue-promoter as encompassed by the instant claims. Applicant has not provided guidance as to which regions in SEQ ID NO: 16 would tolerate such multiple deletions. Examiner agrees that one skilled in the art would know the location of TATA box, CAAT and other non-specific promoter elements in a promoter. However, the activity of a promoter is not determined only by the location of non-specific promoter elements such as the TATA box and CAAT signal, but rather is controlled by a complex set of positive and negative interactions between specific and non-specific promoter elements, and any modification to such interactions results in the

loss of tissue-specific activity or the loss of promoter activity. These interactions also vary between promoters of different tissue-specific activities. Absent specific guidance as to where multiple deletions can be applied in SEQ ID NO: 16 so as the resultant variant will retain male-tissue specific and auxin responsive activities, the claimed invention is not enabled through out the broad scope, as stated in the last Office action.

4. With respect to the disclosed ZmAxig1 promoters of 661bp (of V1) and the 1306 pb (of V2), it is noted that the 661 bp promoter is a fragment of SEQ ID NO:3 which differs from the 1306 bp promoter by only two nucleotide positions. The sequence identity between SEQ ID NO:3 and 16 is more than 99%. Therefore, Applicant's assertion that several points of specific guidance with respect to modification of the disclosed sequences is not correct.

5. With respect to *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), the court has determined that several claims were not supported by an enabling disclosure because of the relatively incomplete understanding of the biology of cyanobacteria as of the filing date of that application and the limited disclosure the particular cyanobacterial genera operative in the claimed invention. Similarly, in the instant application, the claims drawn to sequences having 75% sequence identity and operable fragments are not supported by an enabling disclosure, given the state of the art with respect to multiple deletions of tissue-specific promoter, and the limited working example in the specification. Therefore, the cited case law does not appear to support Applicant's position.

Regarding Kim (1994) and Benfey (1990), the Examiner maintains that the references are applicable because Applicant has not provided evidence to show that multiple deletions of male tissue-specific and auxin responsive promoter elements that retain the tissue-specific promoter activity are routine in the art as of the filing date of this application. Absent such evidence, the rejection to "operable fragments" of the disclosed sequences may be maintained.

Claims 45-48 are included in the rejection because Applicant has not provided guidance for all polynucleotides that are amplified from *Zea mays* nucleic acids using a primer comprising SEQ ID NO: 6, 7, 8, 9 or 10, said polynucleotide having transcriptional regulatory element responsive to auxin. Note, the word comprising implies that primers other than SEQ ID NO:6-10 are also included. To claim such polynucleotides without specific guidance with respect to specific primers and PCR conditions, the claimed invention is not more than an invitation to experiment requiring undue experimentation.

Upon further search of the amended claims and upon further consideration, it is determined that SEQ ID NO: 3 and 4 can be examined with SEQ ID NO: 16, without any additional search. Applicant is welcomed to amend the claims to include SEQ ID NO: 3 and 4.

Written Description

6. Claims 15-32 and 41-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action of 03/12/03.

Applicant's arguments filed 6/12/03 have been fully considered but are not deemed persuasive.

Applicant argues that the claimed invention meets the written description requirement, given the disclosed complete and partial structures of the ZmAxig 1 transcriptional regulatory elements, i.e., SEQ ID NO: 16, 3, 4, and the 661 bp promoter sequences, as well as hybridizing properties of the claimed polynucleotides, specific primers, functional characteristics, and a method of making the claimed invention. (response, page 18-19). Applicant asserts that the instant case is not analogous to *Eli Lilly* situation because unlike Eli Lilly, the claimed invention is well defined by structure involving a subset of sequences of SEQ ID NO: 16 having transcriptional and auxin responsive activity (response, page 20). Applicant finally argues that the requirement by the Office to limit the claimed invention by the disclosed sequences is neither supported by the *Eli Lilly* case law nor the Guidelines of the Written Description Requirement cited by the Examiner (response page 21).

These arguments are not persuasive. The written description requirement for a claimed genus can be satisfied through sufficient description of a representative number of species by relevant identifying characteristics. In support of the broadly claimed genus the specification describes SEQ ID NO: 3, 4 and 16 from a single plant species. These three disclosed promoter sequences share more than 99% sequence identity. There is no evidence in record which shows these three closely related sequences from

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a single plant species are a representative species of the genus of the claims, namely, any and all polynucleotides having at least 75% sequence identity of SEQ ID NO: 16 and operable fragments thereof, any and all hybridizing sequences thereof having transcriptional regulatory and auxin responsive activity as well as polynucleotides amplified from zea mays nucleic acids using a primer comprising SEQ ID NO: 6, 7, 8, 9, or 10. One skilled in the art would not expect that most of these variants will possess the desired promoter activity because of the substantial variation in structures among the polynucleotides. In addition, Applicant has not identified structural features that are unique to members of the genus, and a literature review does not indicate that such features are well known to a skilled artisan. Therefore, the rejection is proper under the cited case law and the guidelines of the written description.

Finally, Applicant's arguments that the application provides support for deletion analysis and directed mutagenesis which the skilled artisan would use in determining auxin-responsive regulatory elements are not persuasive because the description of the claimed invention is not for those in the art to determine. The description of the claimed invention must be supplied by the specification.

Therefore, given the lack of representative species of the genus of the claims as discussed above and in the last Office action, one skilled in the would not recognize from the specification that Applicant was in possession of the claimed invention at the time of filing. The rejection is maintained.

Remarks

Claims 37-40 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other from Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

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A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600